DOCKET NO. SUD-001-USA-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Y. SAKAI, et al.

Serial No.: **To Be Assigned** Art Unit: **To Be Assigned**

Filed: **Concurrently herewith** Examiner: **To Be Assigned**

For: **Nonantigenic Stabilizer And Physiologically Active Substance**

PRELIMINARY AMENDMENT

BOX PRELIMINARY AMENDMENT
Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

In the matter of the above identified application, before assigning a serial number thereto, kindly undertake the following changes:

IN THE SPECIFICATION:

After the title, and before line 1 of the specification, kindly insert the following:

--This application is a continuation-in-part application of parent application serial No. 08/780,086, originally filed on December 23, 1996, now abandoned.--

Kindly replace the original respective paragraphs of the specification with the amended paragraphs as follows:

Page 3, last paragraph:

The nonantigenic stabilizer involved in the present invention therefore is characterized in that it is mainly composed of a peptide whose molecular weight is greater than 0, but not more than 20,000 and whose amino acid sequence is $(Gly\text{-}X\text{-}Y)_n$ that is obtained by a specific decomposition of gelatin or collagen using a collagenase. Particularly, the nonantigenic stabilizer involved in the present invention preferably comprises the peptide composition which is obtained by a specific decomposition of gelatin or collagen using a collagenase, and contains not less than 70% of peptide whose molecular weight is greater than 0, but not more than 20,000 and whose amino acid sequence is $(Gly\text{-}X\text{-}Y)_n$. In particular, the nonantigenic stabilizer involved in the present invention preferably contains at least 85%, more preferably 95% of said peptide to increase nonantigenicity.

Page 5, second paragraph:

There is a fear of antigenicity appearing with even those peptides with an amino acid sequence $(Gly\text{-}X\text{-}Y)_n$ that are obtained by specific decomposition of gelatin or collagenase using a collagenase if they have a molecular weight over 20,000. The nonantigenic stabilizer involved in the present invention has a molecular weight which is greater than 0, but not more than 20,000. Thus it can be prepared with a higher yield from the same raw material than that with a molecular weight not more than 1,000.

The nonantigenic stabilizer involved in the present invention preferably has a molecular weight not more than 10,000 to raise its nonantigenicity. Preferably, the percentage of the peptides whose molecular weight is not over 10,000 in those peptides of the nonantigenic stabilizer involved in the present invention whose molecular weight is not more than 20,000 and whose amino acid sequence is $(Gly\text{-}X\text{-}Y)_n$ is not less than 90%.

REMARKS

The specification has been amended to add additional subject matter pertaining to the molecular weight range of the peptide, and to show the relationship to the parent application which will become abandoned as of the date the U.S. Patent Office accepts as the filing date of this new continuation-in-part application.

It is respectfully submitted that this application is now in condition for examination on the merits and early action and allowance thereof is accordingly respectfully requested.

Respectfully submitted

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MARKED-UP VERSIONS OF AMENDED PARAGRAPHS PURSUANT TO 37 C.F.R. 1.121:

Page 3, last paragraph:

The nonantigenic stabilizer involved in the present invention therefore is characterized in that it is mainly composed of a peptide whose molecular weight is greater than 0, but not more than 20,000 and whose amino acid sequence is $(Gly\text{-}X\text{-}Y)_n$ that is obtained by a specific decomposition of [zelatin] gelatin or collagen using a collagenase. Particularly, the nonantigenic stabilizer involved in the present invention preferably comprises the peptide [composite] composition which is obtained by a specific decomposition of [zelatin] gelatin or collagen using a collagenase, and contains not less than 70% of peptide whose molecular weight is greater than 0, but not more than 20,000 and whose amino acid sequence is $(Gly\text{-}X\text{-}Y)_n$. In particular, the nonantigenic stabilizer involved in the present invention preferably contains at least 85%, more preferably 95% of said peptide to increase nonantigenicity.

Page 5, second paragraph:

There is a fear of antigenicity appearing with even those peptides with an amino acid sequence $(Gly\text{-}X\text{-}Y)_n$ that are obtained by specific decomposition of [zelatin] gelatin or collagenase using a collagenase if they have a molecular weight over 20,000. The nonantigenic stabilizer involved in the present invention has a molecular weight which is greater than 0, but not more than 20,000.

Thus it can be prepared with a higher yield from the same raw material than that with a molecular weight not more than 1,000. The nonantigenic stabilizer involved in the present invention preferably has a molecular weight not more than 10,000 to raise its nonantigenicity. Preferably, the percentage of the peptides whose molecular weight is not over 10,000 in those peptides of the nonantigenic stabilizer involved in the present invention whose molecular weight is not more than 20,000 and whose amino acid sequence is $(Gly\text{-}X\text{-}Y)_n$ is not less than 90%.